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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,954	01/31/2002	Gregory Blair Lamb	1855.4	4572

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EXAMINER
LUCAS, ZACHARIAH

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/062,954	Applicant(s) LAMB, GREGORY BLAIR	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-8 and 10-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6 and 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group II in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-8 and 10-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

Information Disclosure Statement

3. The information disclosure statements (IDS) submitted on March 11, 2002 and February 10, 2003, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 9, 21, 22, and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are each drawn to methods of treating patients with a spinal injury or disorder with a paralyzing agent. Thus, the claims describe methods of using a genus of products identified by their ability to induce a particular effect.

The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description requirement for a generic claim covering several distinct inventions:

> The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice..., reduction to drawings..., or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus... See Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.
>
> A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

Thus, when a claim covers a genus of inventions the specification must provide written description support for the entire scope of the genus. Support for a genus is generally found where the applicant has provided a number of examples sufficient so that one in the art would recognize from the specification the scope of what is being claimed.

In the present case, the application describes the use of only the Botulinum toxin. App., Page 2 (stating "The present invention is directed to a novel method for treating pain using botulinum toxin"). The application does not describe the use of any other paralyzing agents, or provide any guidance as to any other such agents. Because the application states that it is directed towards to the use of the botulinum toxin, and because it does not teach the use of any

other paralyzing agent, the application does not provide sufficient written description support for methods using any paralyzing agent.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 9, 21-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of Donovan (U.S. Patent 6,500,436), Aoki et al. (U.S. Patent 6,290,961), further in view of Share (U.S. Patent 3,903,301) and of Borodic et al., (Drug Safety 11(3): 145-52). These claims read on methods of treating a patient with a spinal compression disorder by administering paralyzing agents, including botulinum toxin A, to the patient.

Donovan teaches that spasticity is a serious complication to any spinal cord injury. The reference further teaches the administration to the patient of a botulinum toxin, including the A toxin, through either intrathecal, or by intramuscular routes. Columns 9-10. Thus, the reference teaches the use of botulinum toxin to treat patients with spinal cord injury. Further, the Share reference also teaches that muscle spasticity may be caused by trauma to the spine. Column 1, lines 24-41. However, the Donovan reference teaches that the toxin is useful for the inhibition of pain, and does not teach that the pain may be inhibited by muscle paralysis.

Aoki teaches methods of relieving pain associated with muscle contractions (spasticity) by administering agents that paralyze the muscles to the muscles. Col. 1, lines 25-35, and column 2, lines 53-64. The agents disclosed for this purpose are the botulinum toxins, including the A toxin. Id. The reference also teaches that toxin should be administered intramuscularly into the spastic muscle. Columns 3-4. Further, the reference teaches that the dosage of the toxin to be administered depends on a number of factors. Column 4, lines 41-49. From these two references, it would have been obvious to those in the art to have used the toxin to induce paralysis in any muscle that, by contracting, was causing pain. Further, from the teachings of Donovan, such would have been particularly obvious in those situations involving pain from spinal cord injury. From the teachings of Aoki and Borodic, it would have been obvious to administer the toxin to the muscles that are causing the pain, and thereby inducing paralysis of those muscles.

While these references do not specifically indicate that the toxin may be administered to spinal muscles, such administrations are also known in the art. For example, the Borodic reference (Drug Safety, 11(3): 145-52), teaches, on page 146, the injection of the toxin into the paraspinal muscles of rabbits, thereby suggesting the use of the toxin in analogous muscles of humans. See also, Rasmussen (Ugeskrift for Laeger, 162(48): 6557-61 (Medline abstract, teaching that botulinum toxin is useful in the treatment of spasticity in the paravertebral muscles). Thus, it would have been obvious to those in the art to have administered the toxin to reduce pain and/or spasticity in the paraspinal muscles, including the intrinsic muscles, of the patient.

Although the dosages of claim 25 are not taught in the references, it would have been obvious to one of ordinary skill in the art to adjust the dosage formulation for the particular use

for which it is applied. See, Aoki, col. 4, supra. Thus, while the references do not teach the particular dosages claimed, the teachings therein render the dosages obvious optimization of the administered composition. See MPEP § 2144.05 II. The claimed methods are therefore obvious in view over the teachings of the prior art.

8. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan, Aoki, Borodic, and Share as applied to claim 9 and 23 above, and further in view of Moyer et al. (WO 00/15245). Claims 26 and 27 further limit the method of the claims described above to embodiments wherein the botulinum toxin is administered, respectively, in a single injection, or as a plurality of injections. Moyer also teaches the use of the toxin to muscle induced pain from spinal injury, or other back pain. Page 4, lines 8-27. The reference also teaches that the toxin can be administered intramuscularly, and may be injected either through a single, or through multiple injections. Page4, lines 28-32, and page 14, lines 16-19. It would therefore have been obvious to those in the art to have used either a single or multiple dose of the toxin to treat patients with a spinal cord injury.

9. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donovan, Aoki, Borodic, and Share as applied to claims 9 and 21, and 22 above, and further in view of the teaching of either of De Simone (U.S. Patent 6,037,373), or Ferree (U.S. Application Publication 2002/0032155). Claim 28 describes a method of treating a disc herniation or degenerative disorder by administering to the patient Botulinum toxin, and by also administering to the patient a factor to enhance healing of the disc. As indicated above, the Botulinum toxin is taught as

effective for reducing the pain of a person with a spinal cord injury. However, the references do not teach that such treatments are effective for improving the repair of the spinal injuries.

Ferree and De Simone each teach methods of administering compositions including (or inducing the production of) factors for the improvement of a disc herniation or degenerative disorder. See, Ferree, claim 1, and De Simone, claims 1 and 2. It is prima facie obvious to combine two compositions, each of which is taught to be useful for the same purpose. See e.g. MPEP § 2144.06. In the instant case, the claims are drawn not to the combination of compositions, but to the combination of therapies for the same disorder, the treatment of the pain, and the therapy to induce healing. Both of these therapies for spinal injury are known in the art as described above. In view of the knowledge of such therapies, and the fact that both are disclosed as useful for treating the same disorder, it would have been obvious to have combined these therapies for the treatment of a patient suffering from such a disorder.

Conclusion

10. No claims are allowed.

11. The following prior art reference is made of record and is considered pertinent to applicant's disclosure. However, while relevant they are also not used as a basis for rejection for the stated reasons.

> Al-Khodairy et al., Spinal Cord, 36:854-58. This reference teaches that the botulinum toxin is effect for treatment in spinal cord injury by reducing pain from muscle spasticity. The reference is considered redundant to the Aoki reference applied above.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 703-308-4240. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Z. Lucas
Patent Examiner
July 21, 2003

JAMES HOUSEL 7/28/03
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